Pony FX

Desktop Spirometer

Introducing a milestone in the desktop spirometry market!

Key Features

- △ ***Screening Spirometry (FVC - SVC - MVV, Pre-Post)***
- △ ***High speed thermal printer (ATS compatible) and Large Graphic Color Display***
- △ ***On-screen Pediatric Encouragement Software***
- △ ***Airway Resistance ROC***
- △ ***Integrated Digital Oximeter***
- △ ***Automatic BTPS Correction***
- △ ***USB and RS 232 PC interface***
- △ ***USB printer interface***
- △ ***Battery and mains operating***

Overview

Pony FX is the new desktop spirometer designed by COSMED for lung function screening. Pony FX is the latest expression of the famous Pony, one of the worldwide best sellers' spirometers introduced for the first time in 1986 and sold in more than 20.000 units. Pony FX includes all the experience, latest requirements and customer wishes collected in more than 20 years.

Accuracy

The turbine flowmeter ensures maximum precision throughout a wide range of flows (up to 20 l/s) with a very low flow resistance (less than 0.7 cm H_2O/l/s at 12 l/s). Pony FX has a built-in temperature sensor for correcting the results automatically to BTPS conditions. A quality control software prompts messages during tests to ensure proper results.

ATS/ERS Compliance

COSMED's turbine flowmeter complies with ATS and ERS recommendations. All flow and volume measurement systems are pre-tested in our lab by means of a pulmonary waveform generator system according to ATS 94 standards (24+26 curves, BTPS conditions). Pony FX meets ERS' 93 recommendations for spirometry.

Ultimate PC Software

Two different operating modes are available.

Data download

Test results stored in the flash memory of the spirometer are downloaded in the PC database for permanent archiving.

PC-Online

Spirometry tests and calibration are managed through the PC allowing real-time display on the PC screen.

Connectivity

Pony FX is provided with 3 different interfaces:

- USB-B (interface with PC)
- USB-A (direct printing with inkjet or laser printers)
- RS232 (interface with PC or other devices as pulse oximeter).

No other spirometer can offer such a wide range of possibilities.

COSMED
Pulmonary Function Equipment

Hardware Features

User Interface

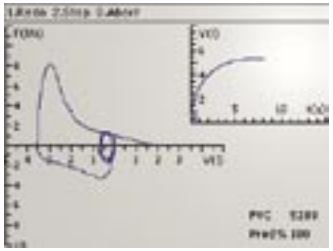
Pony FX has been designed to be easy to use in any environment either hospital or private practice. The internal software follows a typical structure of a PC software with menus and input fields similar to a Windows® or Palm™ OS application. The result is to have introduced the most performed desktop spirometer available in the market so far.

Patient Database

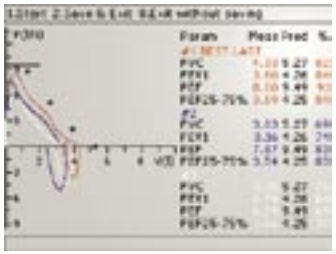
Pony FX is provided with an alphanumerical keyboard that allows to enter complete information about the patient. Letters can be input through keys in the same way most mobile phones work.

Spirometry Tests

All tests can be carried out by simply pressing two buttons. Software shows both inspiratory and expiratory flows during real time.



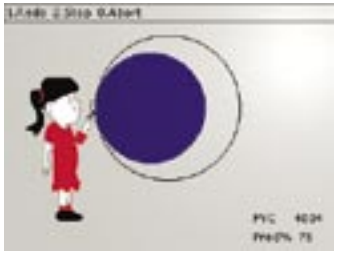
During a test session, up to three Flow/Volume loops can be displayed on a same graph and the best is automatically selected by the software. When the session is over the user can decide which test to save in the archive.



LCD color display allows Pony FX to clearly show up to three Flow/Volume loops on the same screen.

Pediatric Encouragement

This standard feature is particularly indicated for pediatric assessment or for those patients that do not collaborate during FVC manoeuvre. In this mode Pony FX shows an incentive picture during FVC manoeuvre.



When selected, the encouragement is shown in real-time on the display.

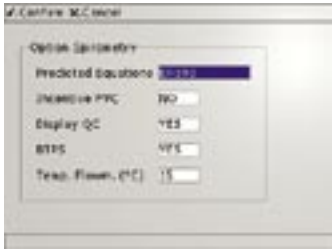
Broncho-Challenge Tests

Pony FX has been designed to manage completely any kind of bronchial challenge tests. When a "Post Test" is selected, software asks whether the user wishes to perform a Broncho-Constrictor or Broncho-Dilator challenge. User can input information about drug used and proceed with a FVC manoeuvre. At the end of the session Pony FX displays both Pre and Post test, data and loops.

Fall of FEV1 and P10, P15 and P20 are also shown on the display and can be printed out by thermal printer.

Settings

Pony FX has been designed to meet most of user needs. The system has most of the features that can be customized according to the purpose of use.

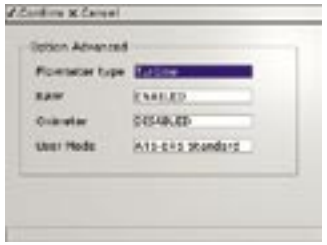


- Norm values can be selected from a long list of available sets of predicted equations.

» International settings can be easily changed according to the country standards.

Pony FX is provided with alphanumerical keyboard and with a "Scroll Control" to access main function easily and fast.

» Hardware settings are easy to change in case new options are included in the Pony FX. No internal changes are required to integrate additional modules.



Printout Reports

» Pony FX can print test reports both through the built-in thermal printer and directly on an USB external printer for A4/letter format reports.

» ***New Features***

Optional Hardware Features

Airway Resistance (ROC)

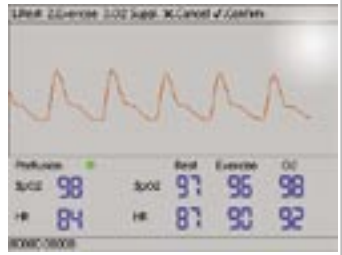
Pony FX can be optionally requested with a kit for performing Airway Resistance. Test is carried out by means of a different handle, incorporating latest technology, for measuring RAW through the occlusion technique. Pony FX in its standard version is already compatible with the ROC option even if purchased in a second time. The ROC handle installation is easy and doesn't require any change in the unit, just plug the cable in the ROC port on the back of the unit and you are ready to measure Airway resistances.

» ***An ergonomic and compact handle allows to turn the Pony FX in a more complete PFT equipment able to perform Airway Resistance (ROC) tests.***

Integrated Digital Oximeter

The Pony Fx oximetry option consists of an integrated probe that is clipped on a subject's finger and is simply connected to the FX unit. The Pony FX displays in real time the Oxygen saruration at rest, at rest with supplemental O_2, under exercise and under exercise with supplemental O_2. A pulse waveform graph and the HR value are measured and recorded too.

» ***SpO_2 option can be integrated just by plugging the interface cable and the probe to one of the ports available in the instrument.***



Software Features

- Complete database management for patients, diagnosis, clinical report, broncho-challenge protocols.

- Easy management of broncho-challenge test by means of user-defined protocols.
- Detailed printing of F/V, V/t, broncho-challenge response graphics, PD 10, 15 and PD 20 calculation.
- Pre-Post test with either broncho-dilator or metacholine.
- Powerful post analysis on data with possibility to overlap tests performed in different test sessions.

» Trend analysis on multiple parameters.

» Software encouragement tool for pediatric or non-cooperative patients.

- More than six selectable sets of predicted values.
- Create custom parameters and user defined set of predicted equations.

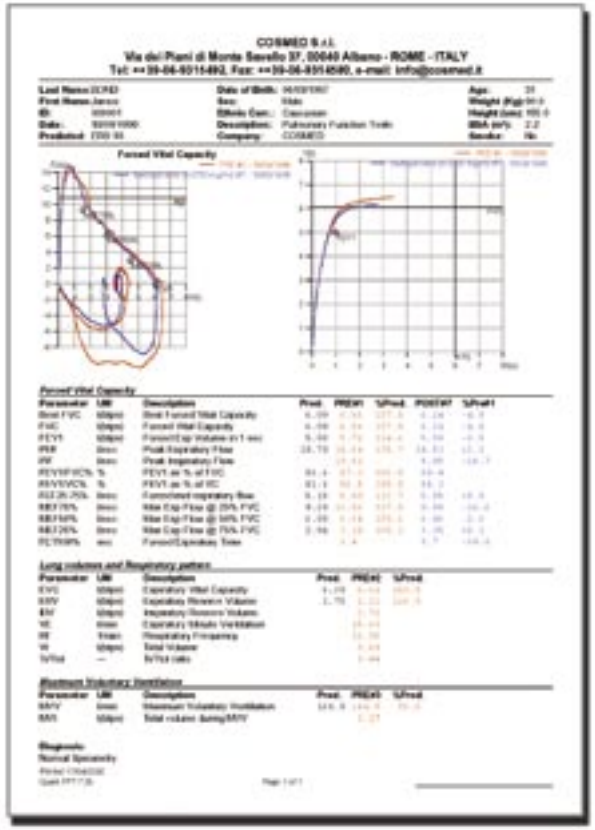
» New NHANES III predicted equations included.

» FEV6 parameter and related calculations now measured.

- Printout report according to the ERS-ATS requirements.
- Create custom printouts according to user settings.
- Automatic interpretation according to latest ATS recommendations.
- Best Test selection and results reproducibility according to ATS 1994 standards.
- Quality control messages according to the ATS guidelines for spirometry tests.

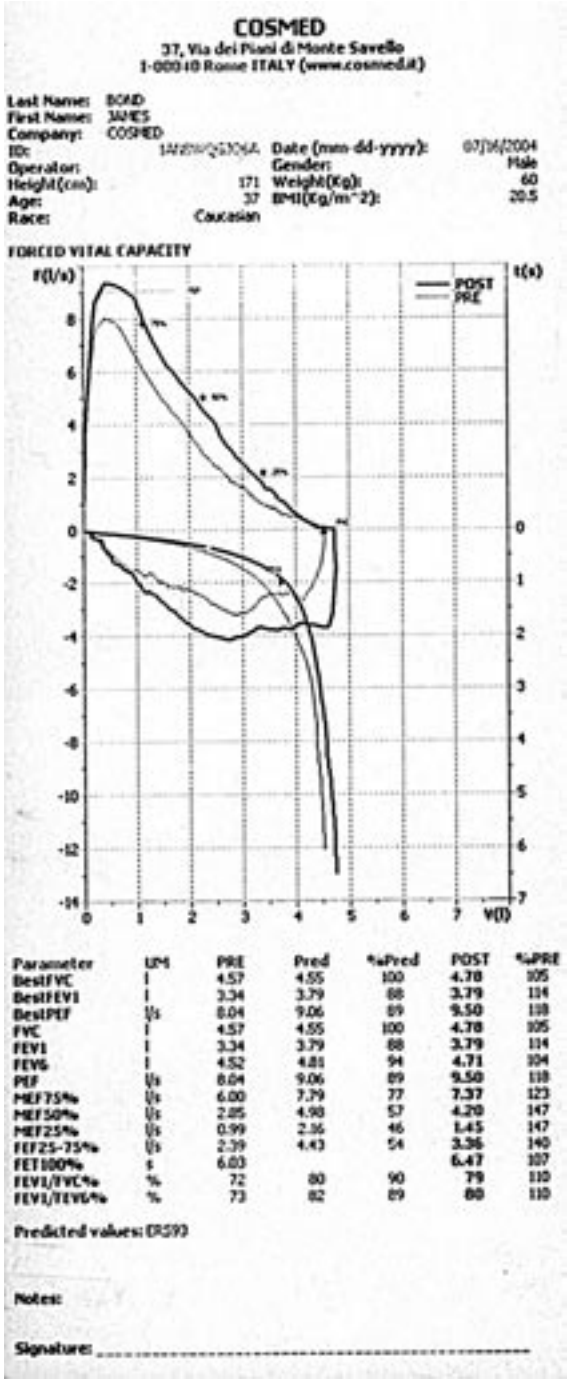
- Full compatibility of the database with Quark PFT product line.

» Pediatric encouragement is done through a "Blow in the bubble" illustration. Real time Flow/volume loops are shown simultaneously during incentive for a better quality control.



A4/Letter format reports can be printed out through PC or by connecting Pony FX directly to a USB printer.
Powerful reporting allows user to printout either ATS or user defined reports.

Printout Reports


COSMED
37, Via dei Piani di Monte Savello
I-00040 Rocca ITALY (www.cosmed.it)
Last Name: BOND
First Name: JAMES
Company: COSMED
Date (mm-dd-yyyy): 07/16/2004
Gender: Male
Weight(Kg): 60
BMI(Kg/m^2): 20.5
Age: 37
Race: Caucasian
FORCED VITAL CAPACITY
F(l/s)
V(l)
t(s)
POST
PRE
Parameter UM PRE Pred %Pred POST %PRE
BestFVC l 4.57 4.55 100 4.78 105
BestFEV1 l 3.34 3.79 88 3.79 114
BestPEF l/s 8.04 9.06 89 9.50 118
FVC l 4.57 4.55 100 4.78 105
FEV1 l 3.34 3.79 88 3.79 114
FEV6 l 4.52 4.81 94 4.71 104
PEF l/s 8.04 9.06 89 9.50 118
MEF75% l/s 6.00 7.79 77 7.37 123
MEF50% l/s 2.05 4.98 57 4.20 147
MEF25% l/s 0.99 2.36 46 1.45 147
FEF25-75% l/s 2.39 4.43 54 3.36 140
FET100% s 6.03 6.47 107
FEV1/FVC% % 72 80 90 79 110
FEV1/FEV6% % 73 82 89 80 110
Predicted values: ERS93
Notes:
Signature:

Pony FX prints comprehensive and full reports on the built-in printer. In alternative reports can be printout on a commercial USB external printer.

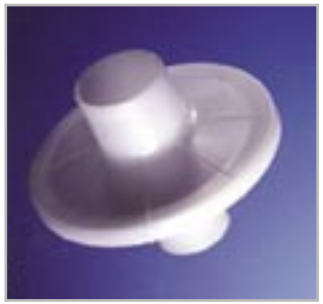
Software Features

Test Reference Table	Standard	Option
Spirometry		
Forced Vital Capacity (Pre-Post)	•	
Slow Vital Capacity	•	
Respiratory Pattern	•	
Maximum Voluntary Ventilation	•	
Broncho-Challenge Test		
Broncho-Dilator Test	•	
Metacholine Challenges	•	
PD10, 15, 20 Response Curve	•	
Airway Resistance (ROC)		
RAW		•
Integrated Pulse Oximeter		
SpO_2		•
Heart Rate		•
Pulse waveform		•

Anti-Bacterial Filters

Use COSMED filters (single patient use) for spirometry.

- Bacterial/Viral 99.9999% efficiency.
- Resistance 0.7cmH_2O/L/s at 720L/min.
- Complies with ATS (American Thoracic) standards.
- Independently tested at Nelson Laboratories USA.



P/N # A 182 300 004 (box of 50 pcs.).

Hardware Features

PC Configuration Required

- Pentium or faster
- Windows XP, 2000, 98 or NT
- 32 Mb RAM or more
- Available USB port
- CD-Rom Drive
- 20 Mb on HD space available
- Monitor VGA, SVGA, XGA
- Any mouse and printer compatible with the MS Windows™ operative system

Options/Accessories

- Calibration syringe (3 liters)
- Antibacterial filters
- Integrated Digital Oximeter
- SpO_2 Finger Probe
- Airway Resistance (ROC) Kit

The optional 3 liters calibration syringe PN C00600-01-11.

Standard Equipment

- PC software and user manual
- Turbine flowmeter
- AC/DC adapter (110-240V)
- USB communication cable
- Carrying case
- Pediatric mouthpiece adapter
- Mouthpieces and nose clips
- Anti-Bacterial filters
- High quality thermal paper

Pony FX is supplied with an elegant case for easy carrying.

Technical Specifications

Flowmeter

Bidirectional digital turbine Ø 28mm

Flow range:	0.03-20 l/s
Volume Range:	12 liters
Flow resistance:	<0.70 cm H_2O/l/s @ 12 l/s
Accuracy F/V:	±2%
Temperature sensor:	0-50° C

Tests

Forced Vital Capacity, Slow Vital Capacity (Inspiratory & Expiratory), Maximum Voluntary Ventilation, Respiratory pattern, Broncho-challenge tests.

Measured parameters

FVC • IVC • VC • MVV • VT • FEV1 • FEV6 • FEV1/FEV6 • FEV6/FVC • PEF • PIF • FEV1/FVC • FEF 25-75 • FEV1/VC% • %FEV1 • MEF25%•MEF50% • MEF75% • FET 100% • ERV • IRV • VE • Rf • ti • te • ti/t.tot • VT/ti • Best FVC • Best FEV1 • IC - SpO2 • HR - R_occ • P_occ • Flow_occ

Predicted values

ERS 1993 (ECCS 1983), NHANES III, Knudson 83, ECCS 1971, ITS, Zapletal, LAM, Pneumobil, Gutierrez (Chile), Multicèntrico Barcelona, user defined predicted calculations.

Available Languages

English, Italian, French, German, Spanish, Portuguese, Turkish, Chinese (Mandarin).

Technical sheet

Power supply:	rechargeable Ni-Mh batteries
Interfaces:	RS 232, USB-A, USB-B
Dimensions:	198x238x76 mm (7.8x9.4x3 in)
Weight:	1200 g (2.6 lbs)

CE

Pony FX meets the European Directive 93/42 on Medical Device.

FDA

510(k) pending (federal law restricts this device to sale by or on the order of a physician)

Safety Standards

EN 60601-1 (safety)/EN 60601-1-2 (EMC)

CE 0476

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